

CLAIMS

I claim:

1. A drug eluting stent-graft, comprising:
a tubular stent having a proximal end, a distal end, a lumen therebetween, and a
5 peripheral wall defining the lumen, wherein the peripheral wall comprises a plurality of
openings,
a biocompatible covering surrounding the stent comprising a textured external
surface layer, and a smooth luminal surface layer facing the lumen of the stent,
a collar coupled to the proximal end of the stent, the collar comprising a wire
10 structure surrounded by the biocompatible covering, an atraumatic proximal end, and a
distal end, wherein the distal end of the collar is coupled to the proximal end of the stent,
and
a drug agent configured to elute from the textured external surface layer and away
from the smooth luminal surface layer of the covering.
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2. The stent-graft of claim 1, wherein the wire structure of the collar is spiral-
wound radially in a tubular plane coaxial with the central axis of the stent.
3. The stent-graft of claim 1, further comprising a plurality of barbs disposed
20 on the distal end of the collar and expandable radially outwardly to anchor the stent-graft
to an interior body wall.
4. The stent-graft of claim 1, wherein the drug agent is a drug chosen from the
group consisting of paclitaxel, sirolimus, an anti-metabolite drug, an antibiotic, a steroid,
25 and a biologically active agent.
5. The stent-graft of claim 1, wherein the drug agent is disposed between the
textured external surface layer and the smooth luminal surface layer of the covering.
- 30 6. The stent-graft of claim 1, wherein the biocompatible covering comprises
ePTFE.

7. The stent-graft of claim 1, wherein the textured external surface layer of the covering comprises a plurality of villi oriented away from the peripheral wall of the stent.

8. The stent-graft of claim 7, wherein the plurality of villi form a plurality of
5 interstices.

9. The stent-graft of claim 7, wherein the plurality of villi comprise villi of varying lengths.

10. The stent-graft of claim 7, wherein the plurality of villi comprise villi of
10 uniform length.

11. The stent-graft of claim 8, wherein the drug agent is disposed within the plurality of interstices.
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12. The stent-graft of claim 1, wherein the textured external surface layer of the covering comprises a plurality of filaments.

13. The stent-graft of claim 12, wherein the drug agent is disposed on the
20 filaments.

14. The stent-graft of claim 1, wherein the textured external surface layer of the covering comprises:

a plurality of individual polygonal shaped cups, each of the cups having a bottom
25 surface, raised side walls, and a plurality of filaments disposed on the bottom surface, wherein neighboring cups have adjacent side walls.

15. The stent-graft of claim 14, wherein the drug agent is disposed on the filaments.
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16. The stent-graft of claim 1, wherein the textured external surface layer of the covering comprises a plurality of nested geometric cells having an intercellular space between each cell.

17. The stent-graft of claim 16, wherein the drug agent is disposed within the intercellular space between each cell of the plurality of nested geometric cells.

5 18. The stent-graft of claim 1, wherein the smooth luminal surface layer of the covering comprises a smooth surface.

19. The stent-graft of claim 1, comprising a plurality of rings of barbs extending along the length of the stent-graft.

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20. The stent-graft of claim 1, wherein the stent is formed from a material chosen from the group consisting of nitinol, titanium, tantalum, niobium, and stainless steel.

15 21. The stent-graft of claim 1, comprising a spot weld at a plurality of openings of the peripheral wall of the stent to secure the textured external surface layer of the covering to the smooth luminal surface layer of the covering.

22. The stent-graft of claim 21, wherein the spot weld is a spot weld chosen
20 from the group consisting of a sintered spot weld, an epoxy application, and an adhesive agent application.

23. The stent-graft of claim 1, wherein the drug comprises a freeze-dried form of the drug.

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24. The stent-graft of claim 1, wherein the covering comprises a separate textured external surface layer and a separate smooth luminal surface layer.

25. The stent-graft of claim 1, wherein the covering comprises a continuous
30 sheet of biocompatible material having the textured external surface layer and the smooth luminal surface layer.

26. A stent-graft, comprising:

a tubular stent having a proximal end, a distal end, a lumen therebetween, and a peripheral wall defining the lumen, wherein the peripheral wall comprises a plurality of openings,

5 a biocompatible textured external surface layer surrounding an outer surface of the peripheral wall of the stent,

a biocompatible smooth luminal surface layer surrounding an inner surface of the peripheral wall of the stent, and

10 a collar having a wire structure surrounded by the biocompatible textured external surface layer and the biocompatible smooth luminal surface layer, an atraumatic proximal end, and a distal end coupled to the proximal end of the stent, wherein the collar is configured to expand and contract in conformity with the stent.

15 27. The stent-graft of claim 26, wherein the wire structure of the collar comprises a plurality of loops, each loop having a proximal end and a distal end.

28. The stent-graft of claim 27, wherein the proximal end of each loop is oriented perpendicular to the central axis of the lumen of the stent.

20 29. The stent-graft of claim 27, wherein the distal end of each loop comprises two barbs.

30. The stent-graft of claim 29, wherein the barbs extend radially away from the stent-graft, and are configured to engage a wall of a body lumen.

25 31. The stent-graft of claim 26, wherein the atraumatic proximal end of the collar comprises a leading edge of biocompatible material coupled to the proximal end of the collar and extending proximal from the wire structure.

30 32. The stent-graft of claim 31, wherein the leading edge has a diameter larger than a diameter of the wire structure.

33. The stent-graft of claim 26, further comprising a drug agent disposed on the textured external surface layer, wherein the drug is configured to elute from the textured external surface layer and away from the smooth luminal surface layer.

5 34. The stent-graft of claim 26, further comprising a drug agent disposed between the textured external surface layer and the smooth luminal surface layer, wherein the drug agent is configured to elute from the textured external surface layer and away from the smooth luminal surface layer.

10 35. The stent-graft of claim 26, further comprising a freeze-dried drug agent configured to elute from the textured external surface layer toward the body lumen wall and away from the smooth luminal surface layer, the drug agent being an agent chosen from the group consisting of paclitaxel, sirolimus, an anti-metabolite drug, an antibiotic, a steroid, and a biologically active agent.

15 36. The stent-graft of claim 26, wherein the textured external surface layer and the smooth luminal surface layer comprise a single biocompatible covering.

37. The stent-graft of claim 26, wherein the textured external surface layer
20 incorporates a texture chosen from the group consisting of a plurality of villi, a plurality of filaments, a plurality of polygonal shaped cups, and a plurality of geometric nested cells.

38. The stent-graft of claim 26, wherein the stent is formed from a material
25 chosen from the group consisting of nitinol, titanium, tantalum, niobium, and stainless steel.

39. A method for supporting a wall of a body lumen, comprising:
providing a stent-graft comprising a tubular stent, a collar coupled to a proximal
end of the stent, the collar having a collapsible structure configured to expand and contract
30 in conformity with the stent, and a plurality of barbs at a distal end of the collar a biocompatible textured covering surrounding an outer surface of the stent/collar, and,
placing a protective sheath over the stent-graft to cover the barbs of the collar,
introducing the stent-graft into a body lumen in a contracted state,

advancing the stent-graft to a desired location within the body lumen,
removing the protective sheath to allow the barbs of the collar to expand radially
outwardly from the stent-graft,
transitioning the stent-graft into an expanded state to place the textured covering
5 into contact with the wall of the body lumen, and
engaging the wall of the body lumen with the plurality of barbs.

40. The method of claim 39, wherein the stent-graft comprises a drug agent
applied to the biocompatible textured covering, the method comprising:
10 eluting the drug agent from the stent-graft to the wall of the body lumen.

41. The method of claim 39, wherein the stent comprises a shape memory
alloy, and the transitioning of the stent-graft into the expanded state occurs without
manual intervention by a user.
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42. The method of claim 39, wherein the transitioning of the stent-graft into the
expanded state is performed using a balloon catheter.

43. The method of claim 39, wherein engaging the wall of the body lumen with
20 the plurality of barbs comprises pushing the stent-graft distally after transitioning the
stent-graft into an expanded state to place the textured covering into contact with the wall
of the body lumen.

44. A method for making a stent-graft, comprising:
25 providing a biocompatible material having a textured surface layer,
placing the biocompatible material onto a mandrel having a body, a proximal end,
and a distal end, wherein the biocompatible material is positioned such that the textured
surface layer faces the body of mandrel,
providing a tubular stent having a proximal end, a distal end, and a peripheral wall
30 with a plurality of openings,
coupling a collar to the proximal end of the stent, the collar having an atraumatic
proximal end, a distal end, and a plurality of barbs extending distally from the distal end,

wherein the collar is coupled to the stent by welding the distal end of the collar to the proximal end of the stent,

positioning the stent and collar over the mandrel and over the biocompatible material,

5 pulling the biocompatible material distally over the peripheral wall until the textured surface layer of the biocompatible material is disposed over the collar and an outer surface of the peripheral wall of the stent,

securing the biocompatible material to the stent using a plurality of welds extending through a plurality of the openings in the peripheral wall of the stent and
10 contacting the biocompatible material, and

removing the stent and collar from the mandrel.

45. The method of claim 44, comprising applying a drug agent to the biocompatible material, wherein the drug agent is applied to the textured surface layer.

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46. The method of claim 44, comprising applying a drug agent to the biocompatible material using a high pressure technique comprising:

providing an airtight, pressurized container containing a drug agent,

placing the biocompatible material within the container, and

20 maintaining an airtight, pressurized environment within the container in order to impregnate the biocompatible material with the drug agent.

47. The method of claim 46, wherein applying a drug agent to the biocompatible material using a high pressure technique is performed prior to placing the
25 biocompatible material on the mandrel.

48. The method of claim 44, wherein the biocompatible material comprises a smooth luminal surface layer, pulling the biocompatible material distally over the collar and the peripheral wall comprises positioning the smooth luminal surface layer along an
30 inner surface of the peripheral wall, and the method further comprises applying a drug agent to the stent-graft by injecting the drug agent into a space between the textured surface layer and the smooth luminal surface layer of the biocompatible material.

49. The method of claim 44, wherein the biocompatible material is a tubular sheet of biocompatible material.

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